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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,929	12/12/2003	Richard S. Ginn	937.03	2257

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EXAMINER

YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

MAIL DATE	DELIVERY MODE
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04/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/734,929

Applicant(s)

GINN ET AL.

Examiner

DIANE YABUT

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received on 12/06/2007.

The examiner acknowledges the amendments made to the claims.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 19 recites the limitation "the bioabsorbable body" in line
8. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by **Brucker** (U.S. Patent No. **6,296,657**).

Claims 1 and 5: Brucker discloses a device for sealing a passage through tissue including a bioabsorbable body **22** comprising a proximal end, a distal end, a diameter, and a lumen extending between the proximal end and the distal end, and a bioabsorbable sealing member **18** disposed within the lumen that is expandable across the lumen for substantially sealing the lumen from fluid flow therethrough, wherein the bioabsorbable body does not expand when exposed to fluid (Figures 1a-1b; col. 5, lines 26-33).

Claims 2-3: Brucker discloses the sealing member **71** comprising an expandable gel foam that is expandable when exposed to the fluid to substantially seal the lumen (Figure 7; col. 5, lines 7-18).

Claim 4: Brucker discloses the sealing member **54** comprises an annular-shaped member (Figure 5; col. 4, lines 40-53).

Claim 6: Brucker discloses the sealing member **32** being biased towards a first configuration for substantially sealing the lumen from fluid flow therethrough, and is movable to a second configuration for accommodating introduction of one or more devices through the lumen, due to the septum valve **30** (Figure 2, col. 3, line 64 to col. 4, line 11).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Brucker** (U.S. Patent No. **6,296,657**).

Claims 9-10: Brucker does not expressly disclose the body having a length of not more than about ten millimeters and having a diameter not more than about twice the length. However, bioabsorbable body **22** can be considered to be elongate (Figures 1a-1b). Also, depending on where the body is to be implanted, it would be obvious to one having ordinary skill in the art at the time of invention to limit the length of the body to not more than about ten millimeters so that the body won't extend out of the wound. Further, if the wound is large, it would have been obvious to one having ordinary skill in the art to have the body's diameter being not more than about twice the length of the body. It also has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

7. Claims 7-8, 19-24, 27-28, 31-35, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Brucker** (U.S. Patent No. **6,296,657**) in view of **Atkinson** (U.S. Patent No. **6,645,225**).

Claims 7-8, 19-24, 27-28, 31-35, and 37: Brucker discloses the claimed device, including a bioabsorbable body or plug member (see paragraph 4 above), except for a connector on the proximal end of the body for detachably securing the body to a delivery device or an elongate shaft extending from the proximal end of the body.

Atkinson teaches a sealing device including a connector **44** on a proximal end of a body **26** having threaded connectors cooperating with a threaded hole **38** of the body for detachably securing the body to a delivery device or elongate shaft **42** extending from the proximal end of the body, the body or plug member lumen extending between the plug member distal end and the elongate distal end, and also an actuator **46** for releasing the plug member from the distal end of the elongate member (Figures 3-4). Atkinson also teaches a second elongate member **12** insertable through the plug member lumen that is disposed beyond the distal end of the plug member and acts as a location indicator and is substantially atraumatic (Figures 11-12; col. 4, lines 27-31). It would have been obvious to one of ordinary skill in the art at the time of invention to provide an elongate delivery device, as taught by Atkinson, to Brucker in order to facilitate delivery of the device into a passage through tissue.

8. Claims 11-15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hermann** (U.S. Patent No. **5,871,474**).

Claims 11-15: Hermann discloses a body **10** comprising a lumen comprising a tapered portion that tapers in cross-section, and an expandable, flexible sealing member ("balloon membrane") **20** comprising a generally annular-shaped member disposed adjacent a wide end of the tapered portion of the lumen, the sealing member being movable or wedged into the tapered portion for substantially sealing the lumen from fluid flow therethrough, wherein the body does not expand when exposed to the fluid (Figure 4).

Hermann does not expressly disclose the body being made of bioabsorbable material or the sealing member comprising a coil of material. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a bioabsorbable material for the body since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use. Also, although the sealing member of Hermann is not comprised of a coil of material, Hermann does teach screw threads **12** which may take the form of a coil and increase the traction of the sealing member within the body to effectively keep it in place.

Claim 18: Hermann does not expressly disclose the body having a length of not more than about ten millimeters and having a diameter not more than about twice the length. However, the body **10** can be considered to be elongate (Figure 4). Also, depending on where the body is to be implanted, it would be obvious to one having ordinary skill in the

art at the time of invention to limit the length of the body to not more than about ten millimeters so that the body won't extend out of the wound. Further, if the wound is large, it would have been obvious to one having ordinary skill in the art to have the body's diameter being not more than about twice the length of the body. It also has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

9. Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hermann** (U.S. Patent No. **5,871,474**) in view of **Atkinson** (U.S. Patent No. **6,645,225**).

Claims 16-17: Hermann discloses the claimed device, except for a connector on the proximal end of the body for detachably securing the body to a delivery device or an elongate shaft extending from the proximal end of the body.

Atkinson teaches a sealing device including a connector **44** on a proximal end of a body **26** for detachably securing the body to a delivery device or elongate shaft **42** extending from the proximal end of the body (Figures 3-4). It would have been obvious to one of ordinary skill in the art at the time of invention to provide an elongate delivery device, as taught by Atkinson, to Brucker in order to facilitate delivery of the device into a passage through tissue.

10. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Brucker** (U.S. Patent No. **6,296,657**) in view of **Atkinson** (U.S. Patent No. **6,645,225**), as applied to claim 21 above, and further in view of **Hermann** (U.S. Patent No. **5,871,474**).

Claim 25: Brucker and Atkinson disclose the claimed device except for the sealing member being movable into a tapered portion in the plug member lumen.

Hermann teaches a body **10** with lumen having a tapered portion that tapers in cross-section, and an expandable, flexible sealing member ("balloon membrane") **20** comprising a generally annular-shaped member disposed adjacent a wide end of the tapered portion of the lumen, the sealing member being movable or wedged into the tapered portion for substantially sealing the lumen from fluid flow therethrough, wherein the body does not expand when exposed to the fluid (Figure 4). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a tapered portion in the lumen of the body with a sealing member disposed inside, as taught by Hermann, to Brucker and Atkinson in order to maintain a tight seal and to facilitate introduction into a passage through tissue.

11. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Brucker** (U.S. Patent No. **6,296,657**) in view of **Atkinson** (U.S. Patent No. **6,645,225**), as applied to claim 28 above, and further in view of **Davis** (U.S. Patent No. **6,143,004**).

Claim 29: Brucker and Atkinson disclose the claimed device, except for the second elongate member comprising a tubular member including a bleed back lumen, and wherein the location indicator comprises a bleed back port on the distal end of the

tubular member, the bleed back port being in communication with the bleed back lumen.

Davis teaches a bleed back lumen **118** and bleed port **114** (Figures 6 and 8). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a bleed back lumen and port, as taught by Davis, to Brucker and Atkinson in order to easily verify proper placement of the device within the body (col. 9, lines 43-37).

Allowable Subject Matter

Claims 26, 30 and 36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

12. Applicant's arguments with respect to claims 1-37 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734
/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731